

**FACE GUARD ADVANCED- octinoxate, octocrylene, titanium dioxide cream cream**  
**Janssen Cosmetics GmbH**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Face Guard Advanced SPF 30**

**Active Ingredient Section**

Active Ingredients: Ethylhexyl methoxycinnamate 7,494%, octocrylene 6%, titanium dioxide (nano) 0,99%

**Other Ingredients Section**

Cosmetic Ingredients: Aqua [water], propylheptyl caprylate, butylenes glycol, methyl glucose sesquistearate, diethylamino hydroxybenzoyl hexyl benzoate, hydrogenated polyisobutene, glycerin, steareth-21, methylene BIS-benzotriazolyl tetramethylbutylphenol, BIS-ethylhexyloxyphenol methoxyphenyl triazine, cetearyl alcohol, pentylene glycol, sodium potassium aluminum silicate, silica, glyceryl stearate, phenyl trimethicone, xanthan gum, ectoin, thermus thermophilus ferment, aluminum hydroxide, glyceryl caprylate, decyl glucoside, lecithin, hydrogen dimethicone, ascorbyl palmitate, tocopherol, BHT, tetrasodium glutamate diacetate, propylene glycol, citric acid, sodium hydroxide, parfum [fragrance], phenoxyethanol, potassium sorbate,

CI 77 891 [titanium dioxide]

**Purpose Section**

UV protection serum, SPF 30, against premature light induced skin aging. With photostable UVA/ UVB filters, Ectoin and biotechnological agents against IR-rays. Ideal for all skin types and for combining with all day care products.

**Direction For Use**

Directions: Simply apply onto the face, neck and neckline after cleansing in the morning and then apply the usual day cream on top.

**Warnings**

Children under six months of age: consult a doctor.

Warning: For external use only. Not to be swallowed. Avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water. Discontinue use if signs of irritation or rash appear. If irritation or rash persists, consult a doctor.

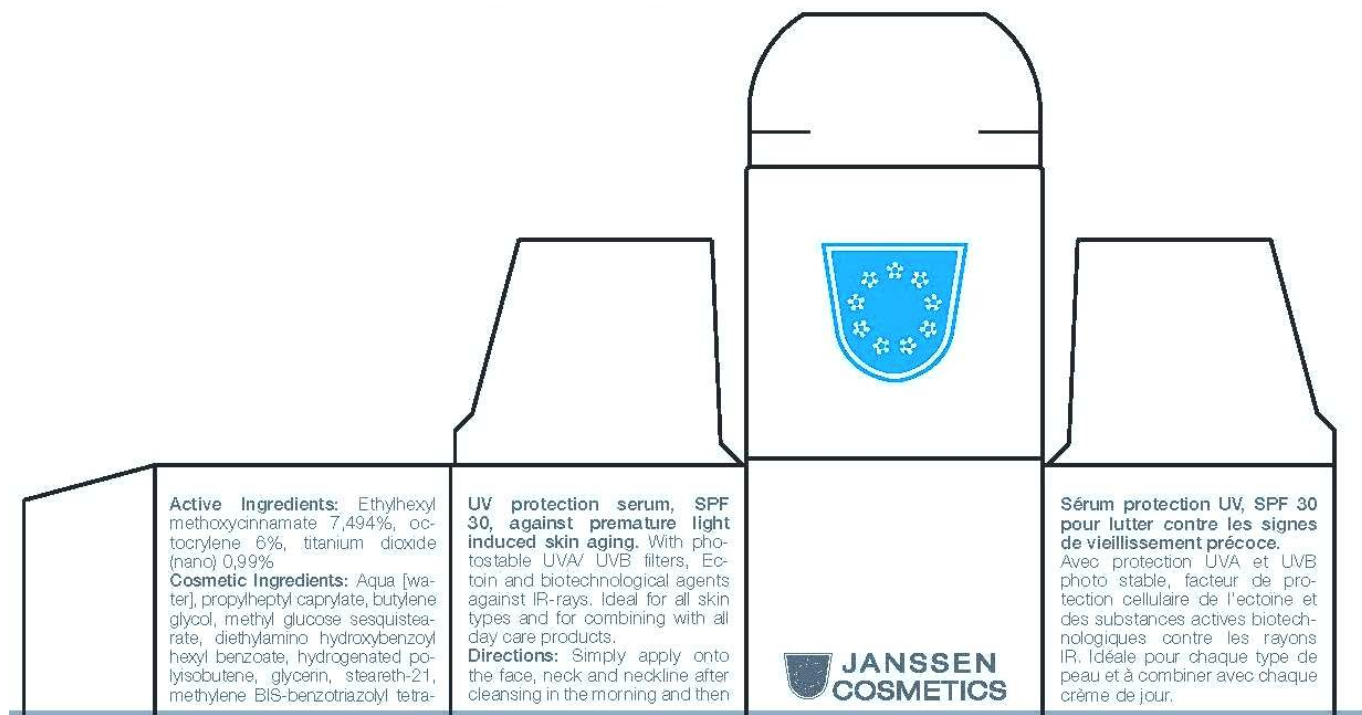
Keep out of reach of children.

**Principal Label - Box and Bottle**

Packaging outside



150.50 mm



methylbutylphenol, BIS-ethylhexyloxyphenol methoxyphenyl triazine, cetearyl alcohol, pentylene glycol, sodium potassium aluminum silicate, silica, glyceryl stearate, phenyl trimethicone, xanthan gum, ectoin, thermus thermophilus ferment, aluminum hydroxide, glyceryl caprylate, decyl glucoside, lecithin, hydrogen dimethicone, ascorbyl palmitate, tocopherol, BHT, tetrasodium glutamate diacetate, propylene glycol, citric acid, sodium hydroxide, parfum [fragrance], phenoxyethanol, potassium sorbate, CI 77 891 [titanium dioxide]



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apply the usual day cream on top. Children under six months of age: consult a doctor.

**Warning:** For external use only. Not to be swallowed. Avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water. Discontinue use if signs of irritation or rash appear. If irritation or rash persists, consult a doctor.

**Keep out of reach of children.**  
**Lichtschutzfluid SPF 30 gegen vorzeitige, lichtbedingte Hautalterung.** Mit photostabilen UVA- und UVB-Filtern, Zellschutzwirkstoff Ectoin und biotechnologischen Aktivstoffen gegen IR-Strahlen. Für jeden Hauttyp geeignet und mit jeder Tagespflege kombinierbar.

**Anwendungshinweise:** Auftragen und gewohnte Tagescreme darüber geben. Kinder unter 6 Monaten: Arzt konsultieren.

**Warnung:** Nur zur äußerlichen Anwendung. Nicht verschlucken. Vermeiden Sie Kontakt mit den Augen. Wenn doch Kontakt mit den Augen entsteht, gründlich mit Wasser ausspülen. Beenden Sie die Anwendung, wenn Sie Anzeichen von Reizung oder Ausschlag feststellen. Konsultieren Sie einen Arzt, wenn die Reizung oder der Ausschlag weiterhin bestehen.

**Außerhalb der Reichweite von Kindern aufbewahren.**

ALL SKIN NEEDS  
OPTIONS TOUTE PEAU

Face Guard  
Advanced  
SPF 30

Soin Protecteur  
Avancé

NET 1.0 FL. OZ. 30ml e

**Guide d'utilisation:** A appliquer sous votre crème de jour habituelle. Enfants âgés de moins de 6 mois: Consulter un médecin

**Attention:** Réservé à l'usage externe. Ne pas avaler. Éviter le contact avec les yeux. En cas de contact avec les yeux, rincer abondamment avec de l'eau. Cesser immédiatement l'utilisation en cas d'irritations ou d'éruption cutanée. Si l'irritation ou une éruption cutanée persiste, consulter un médecin. **Tenir hors de portée des enfants.**

**Suero de protección UV, SPF 30, contra el envejecimiento prematuro de la piel inducido por la luz.** Con filtros fotoestables UVA / UVB, ectoína y agentes biotecnológicos contra los rayos infrarrojos. Ideal para todo tipo de pieles y para combinarlo con todos los productos de cuidado de día.

**Instrucciones de uso:** Distribuir y aplicar la crema de día correspondiente. Niños menores de 6 meses: Consulte a un médico.

**Advertencia:** Sólo para uso externo. No ingerir. Evitar el contacto con los ojos. Si el contacto ocurre, enjuagar bien los ojos con agua. Suspender su uso si aparecen signos de irritación o erupción. Si la irritación o la erupción cutánea persisten, consulte a un médico. **Mantener fuera del alcance de los niños.**

Rez. 1713/05



## FACE GUARD ADVANCED

octinoxate, octocrylene, titanium dioxide cream cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:24653-283
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	0.3 g in 30 mL
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2.248 g in 30 mL
<b>OCTOCRYLENE</b> (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	1.8 g in 30 mL

## Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
METHYL GLUCOSE SESQUISTEARATE (UNII: V1YW10H14D)	
DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE (UNII: ANQ870JD20)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PROPYLHEPTYL CAPRYLATE (UNII: 991Z19V2OD)	
GLYCERIN (UNII: PDC6A3C0OX)	
BEMOTRIZINOL (UNII: PWZ1720CBH)	
BISOTRIZOLE (UNII: 8NT850T0YS)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
STEARETH-21 (UNII: 53J3F32P58)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
THERMUS THERMOPHILUS (UNII: 415H64SACF)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
ECTOINE (UNII: 7GXZ3858RY)	
THERMUS THERMOPHILUS LYSATE (UNII: 775R692494)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
TOCOPHEROL (UNII: R0ZB2556P8)	
BUTYLENE GLYCOL MONOLAURATE (UNII: 2Z947R568V)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24653-283-02	1 in 1 BOX	06/01/2016	
1	NDC:24653-283-01	30 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/01/2016	

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**Labeler** - Janssen Cosmetics GmbH (499187946)

**Establishment**

Name	Address	ID/FEI	Business Operations
Janssen Cosmetics GmbH		499 18 79 46	manufacture(24653-283)

Revised: 6/2016

Janssen Cosmetics GmbH